510(k) Summary	
Name of Firm:	Synthes USA 1302 Wrights Lane East West Chester, PA 19380
510(k) Contact:	Heather Guerin Sr. Regulatory Affairs Specialist Telephone: 610-719-5432 Facsimile: 610-719-5102 Email: guerin.heather@synthes.com
Date Prepared:	September 6, 2011
Trade Name:	Synthes XRL System
Classification:	21 CFR 888.3060–Spinal intervertebral body fixation orthosis Class II Orthopedic and Rehabilitation Devices Panel Product Code: MQP
Predicates:	Synthes SynMesh Spacer System (K003275) Synthes Synex System (K003836) Synthes Contoured SynMesh (K041389) Alphatec NOVEL VBR Spinal System (K050553) Synthes Oracle Spacer System (K062933)
Device Description:	The Synthes XRL System is an addition to Synthes' existing thoracolumbar vertebral body replacement systems. These implants are designed to replace a collapsed, damaged or unstable vertebral body and provide anterior spinal column support. These additional implants include telescoping cylindrical components with spiked endplates to grip the adjacent vertebral bodies. These devices are manufactured from PEEK (ASTM F1579-02e1 and ASTM D 6262) with titanium (ASTM F 1295) locking rings and stop pins and tantalum (ASTM F 560) radiopaque markers.
Intended Use/ Indications for Use:	The Synthes XRL device is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged or unstable vertebral body due to tumor or trauma (i.e., fracture). The Synthes XRL device is intended to be used with Synthes supplemental internal fixation systems (e.g., USS, including Matrix and Pangea, and TSLP). The interior of Synthes XRL can be packed with bone (i. e., autograft or allograft). The Synthes XRL device is designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

510(k) Summary	
Comparison of the device to predicate device(s):	The Synthes XRL System is a result of design modifications to predicate devices. It is substantially equivalent to the predicates in design, function, material and intended use.
Performance Data	Synthes performed the following testing based on ASTM F2077 and ASTM F1717: • Static and Dynamic Axial Compression • Static and Dynamic Axial Torsion • Expulsion • VBR Height-Locking Test Bench testing results demonstrate that the Synthes XRL System is substantially equivalent to the predicate devices. Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 2 0 2011

Synthes USA
% Ms. Heather Guerin
Sr. Regulatory Affairs Specialist
1302 Wrights Lane East
West Chester, Pennsylvania 19380

Re: K103320
Trade/Device Name: Synthes XRL System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: October 14, 2011
Received: October 17, 2011

Dear Ms. Guerin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®

4 Indications for Use Statement

510(k) Number: K103320
(if known)

Device Name: Synthes Synthes XRL System

Indications for Use:

The Synthes XRL device is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged or unstable vertebral body due to tumor or trauma (i.e., fracture). The Synthes XRL device is intended to be used with Synthes supplemental internal fixation systems (e.g., USS, including Matrix and Pangea, and TSLP). The interior of Synthes XRL can be packed with bone (i. e., autograft or allograft).

The Synthes XRL device is designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

Prescription Use X (21 CFR 801 Subpart D)	AND / OR	Over-the-Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103320